

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 42-57 remain pending in the application subsequent to entry of this Amendment.

The claims have been amended in order to more particularly point out and distinctly claim that which applicant regards as his invention and to address the issues raised on pages 2 and 3 of the Official Action.

More specifically, claims 42 and 43 have been amended to delete terms questioned by the examiner and to reorganize both claims to refer to methods of inhibiting the growth of pathogenic bacteria, virus or fungi in a body cavity or orifice. In claim 43 the last phrase concerning an optional ingredient has been deleted and in claim 44 the last phrase has been deleted as well.

Applicant does not fully understand why a rejection of indefiniteness is directed towards claim 51. Indeed, it is possible to administer these various components depending upon the type of infection or inflammatory condition being treated, for instance, *see* U.S. 5,536,743 mentioning, among other things, ammonium salts. The examiner also seems to recognize this considering, for example, the comments made in the last paragraph of page 6 of the Official Action. *See* also the discussion of U.S. 5,895,648, newly cited and applied in the current Official Action, in particular the discussion found on page 4, fourth full paragraph of the current Official Action. Accordingly, it is submitted that claim 51 is definite and would be well understood by one having ordinary skill in this art. Reconsideration of this rejection is requested.

The balance of the Official Action deals with a reformulated prior art-based rejection of all claims as being unpatentable over Vesely '370 and Ehret '724, of record in this application and thoroughly discussed in previous examinations and responses, taken in conjunction with four newly cited references, all U.S. patents.

First, as to the combination of Vesely '370 and Ehret '724: This combination was discussed in the previous replies to former Office Actions.

In the present Office Action the examiner, quoting the two references, constructs an obviousness objection based on the two elements: Vesely discloses a *Lactobacillus salivarius* which produces hydrogen peroxide that inhibits pathogenic bacteria and Ehret discloses a *Lactobacillus brevis* using arginine.

The applicant does not contest the evidence of the state of the art, but wishes to stress that Ehret does not teach or suggest to combine the arginine utilizing lactic acid bacteria with a lactic acid bacteria producing hydrogen peroxide in order to obtain an enhanced inhibition of the growth of pathogens.

Therefore, the technical effect of the combination of strains herein claimed is not suggested by the two cited references.

The combination of Vesely '370 and Ehret '724 and Tosi '911:

Tosi '911 does not provide an enabling disclosure of the strains listed in column 1, lines 51-58 so that the person skilled in the art would not be able to determine whether the strains used in Tosi '911 can be used in the present invention. For instance, Tosi '911 does not reveal if the *L. gasseri* used is a hydrogen peroxide-producing or a hydrogen peroxide-non-producing strain, therefore, the skilled person is not able to perform the claimed invention.

How the person skilled in the art would have been unable to arrive at the claimed invention from the combined teaching of Vesely and Ehret was already discussed in the previous responses and amendments . It will be noted that Ehret discloses arginine utilizing lactic acid bacteria, but fails to disclose their applicability in a medical field. As applicant's claims are drawn to medical procedures, not compositions, the pertinence of this citation is dubious at best.

Tosi '911 does not reveal whether the strains used produce hydrogen peroxide or use arginine, therefore, the skilled person does not know which of them to select and how to use them.

Some of the additional references cited relate to various dependent claims which deal with additive ingredients. These claims are believed to be patentable for the same reasons as the claims from which they depend but in any event a person skilled in the art would not find any useful information in these additional citations relevant to the subject matter now under review.

Briefly, Crapo '026 discloses a liposome capable of fusion with a cell in order to deliver in the cell an antioxidant. This is a technical problem completely different from the inhibition of pathogens as in the present invention.

Persello '478 deals with particular forms of silica specially adapted for brushing teeth – hardly relevant to applicant's claims. As with Ehret, Persello appears to be cited based on compositions (not claimed) and not relevant to methods.

DE SIMONE

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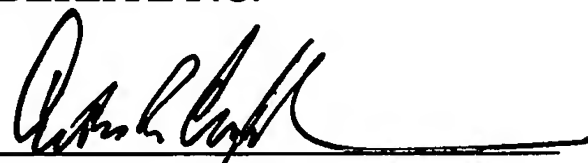
U.S. 5,895,648 teaches a composition intended for feed use as the title indicates, not for medical use. No useful information on how to inhibit pathogens' growth can be found there.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

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